REMARKS

This paper responds to the second Advisory Action mailed December 19, 2007 in the above-captioned application. Claims 1, 4-7, 9-23, 25-27, 32-43, 45-55, 61-70 and 72-86 were pending in this application when a Final Office Action was mailed on May 4, 2007. Applicants' claim amendments, filed on July 5, 2007 in response to the May 4, 2007 Final Office Action, were entered. New claims 87-89 have been added in this response. Accordingly, claims 1, 4-7, 9-23, 25-27, 32-43, 45-55, 61-70, 72-76 and 78-89 are currently pending.

The status of the application in light of the December 19, 2007 Advisory Action is as follows:

(A) Claims 19, 20, 22, 23, 25-27, 32, 35-39, 78, 79, and 86 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,938,688 to Schiff ("Schiff") in view of Patent Application Publication US2002/0087201 to Firlik et al. ("Firlik '201") and Patent Application Publication US2002/0091419 to Firlik et al. ("Firlik '419");

(B) Claims 1, 4-7, 9-12, 14-18, 21, 40-43, 45-47, 49-55, 61-70, 72, 73, 75, 76, 80, 81, and 83-85 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Schiff in view of Firlik '419 and Firlik '201 and further in view of US 2004/0082847 to McDermott ("McDermott") and an article by Jeffrey Binder, titled "Functional Magnetic Resonance Imaging: Language Mapping," (Neurosurgery Clinics of North America) 8.3:383-392 (1997) ("Binder");

(C) Claims 13 and 48 stand objected to as being dependent upon a rejected claim, but are indicated to be allowable if rewritten to be in independent form; and

(D) Claims 74 and 82 are allowed.

A. Response to the Section 103 Rejections on the Basis of Schiff, Firlik '419 and Firlik '201

Claims 19, 20, 22, 23, 25-27, 32, 35-39, 78, 79 and 86 were rejected under 35 U.S.C. § 103 as being unpatentable over Schiff in view of Firlik '419 and Firlik '201 (collectively, "Firlik"). In rejecting the foregoing claims, the Examiner has relied upon Schiff as a primary reference and has relied upon Firlik as supplying elements missing from Schiff. In particular, Schiff is relied upon in the Final Office Action for disclosing the treatment of impaired cognitive functions that can include semantic information processing. The Examiner stated that Schiff's disclosed treatment of cognitive dysfunctions resulting from stroke (Schiff at column 2, line 65) inherently includes treating language-based disorders. Accordingly, Schiff is relied upon for disclosing all the elements of claim 19 except for specifying that the stimulation site is within the patient's skull, proximate to the dura mater and outside a cortical surface of the patient's brain. Firlik is then relied upon for supplying the element missing from Schiff, namely selecting a stimulation site to be within the patient's skull, proximate the dura mater, and outside a cortical surface of the patient's brain.

In the second Advisory Action, the reliance on Schiff was further clarified to include Schiff's disclosure that "in addition to being applied to the patient's intralaminar nuclei or a portion thereof, the electrical stimulation can also extend to other regions of the brain" (Schiff at column 11, lines 29-32). Schiff was also relied upon in the second Advisory Action for the proposition that regions of the cortex may be selected for stimulation through intralaminar projections to those regions.

In particular, the second Advisory Action states

> "therefore, since Schiff specifies that a variety of electrodes can be employed for delivering the electrical stimulation, that the electrical stimulation may extend to other regions of the brain in addition to the intralaminar nuclei and further that regions of the cortex may be selected for stimulation through intralaminar nuclei projections to those regions, it would have been obvious to one having ordinary skill in the art at the time the invention was [made] to modify Schiff such that the method and system includes the electrodes positioned as taught by Firlik '419 and Firlik '201 since such a modification

would provide a means for highly selective deep brain stimulation or both highly selective deep-brain and highly selective cortical stimulation without inducing serious complications from overly invasive placement of electrodes into deep-brain regions."

The foregoing statement in the second Advisory Action apparently relies on Schiff's disclosure that "regions of the cortex may be selected for stimulation through intralaminar projections to those regions" to provide a tie between the deep-brain electrode placement of Schiff and the cortical electrode placement of claim 19. In fact, Schiff does not provide such a tie.

Schiff discloses a method for treating a patient having an impaired cognitive function (Schiff at Abstract, col. 1, ln. 56, and col. 2, ln. 17). Schiff's approach for addressing the patient's cognitive dysfunction is to apply electrical stimulation "to at least a portion of the patient's intralaminar nuclei under conditions effective to relieve the patient's impaired cognitive function" (Schiff at col. 4, lns. 59-62). Schiff further states that "[i]n addition to being applied to the patient's intralaminar nuclei or portion thereof, the electrical stimulation can also extend to other regions of the patient's brain" (col. 11, lns. 29-32).

Schiff also discloses a relationship between cognitive functioning and body movements. For example, Schiff states that "[p]referably, the intralaminar nuclei subdivision which is to receive electrical stimulation is one which projects to an area of the brain which has reduced baseline function but which also exhibits increased function during periods of external stimulation or internally generated stimulation, such as patient's self-generated activity (e.g., head turning)" (col. 12, lns. 46-51). Schiff further states that "other external stimulation that may modulate cognitive function, would include alteration of trunk, head, or limb position signals, such as a vibrational stimulation of the sternocleidomastoid muscle" (col. 13, lns. 1-5).

Schiff's stimulation of the intralaminar nuclei appears to operate by one or more mechanisms. For example, Schiff states that "[o]ne theory of the present invention is that similar event-holding functions tied to head, hand, trunk or other bodily coordinates are generated by intralaminar nuclei stimulation and account for the improved cognitive

functions seen in patients who are externally or internally stimulated" (col. 13, lns. 28-33). Schiff further states that "preferably at least one of the two or more subdivisions and, more preferably at least two of the two or more subdivisions of the intralaminar nuclei to which electrical stimulation is applied modulates the specific cognitive function which is impaired in the patient" (col. 14, lns. 51-55).

To summarize, Schiff stimulates the intralaminar nuclei to address a patient's cognitive impairment. Based on Schiff's disclosure, it appears that stimulating the appropriate intralaminar nuclei subdivision has either an indirect effect on the cognitive function (via projections to cortical populations), or emulates an improvement in the cognitive function resulting from motion of the head, hand, trunk, or other body part.

Schiff nowhere discloses or suggests that the effect Schiff seeks (improvement in cognitive functioning) can be achieved by direct stimulation of the appropriate cortical neural population, rather than through Schiff's indirect cortical effect resulting from stimulation of the intralaminar nuclei. In fact, there is nothing in Schiff that would suggest to one of ordinary skill in the art that the effect Schiff achieves (stimulating the intralaminar nuclei to improve cognitive functioning) can be achieved by direct stimulation of the cortex because such stimulation would necessarily rely on a different mechanism of operation than either of those disclosed by Schiff.

Schiff's statement that "in addition to being applied to the patient's intralaminar nuclei or portion thereof, the electrical stimulation can also extend to other regions of the brain" is the sum total of Schiff's disclosure of regions other than the ILN to which stimulation may be provided in accordance with his method. This broad disclosure is simply not adequate to suggest to one of ordinary skill in the art that the "other regions of the brain" (which encompasses many thousands of potential regions in an extremely complex organ) should be narrowed down to "a stimulation site within the patient's skull, proximate the dura mater and outside a cortical surface of the patient's brain," as is included in claim 19.

Even though Schiff discloses relationships between the intralaminar nuclei and cognitive functions in table 2, Schiff nowhere discloses a relationship between a language disorder and an associated region or subdivision of the intralaminar nuclei. Even though Schiff discloses in table 3 specific intralaminar nuclei subdivisions coupled with "primary cortical targets," Schiff fails to disclose that any of the primary cortical targets correspond to language centers. In addition, Schiff's correlation between the primary cortical targets and the specific intralaminar nuclei subdivisions is used not to select cortical stimulation areas but to select intralaminar nuclei stimulation areas. Specifically, Schiff states that "once the portion of the brain having reduced baseline function is identified, the portion can be correlated with the intralaminar nuclei ("ILN") subdivision which projects to this region, for example, by using table 3" (col. 14, lns. 2-6). Schiff then goes on to state that "further details regarding the correlation of areas of the brain to the intralaminar nuclei subdivisions which project thereto can be found in, for example, Jones et al. (reference deleted). When a subdivision is selected in this manner, electrical stimulation can be applied to the selected subdivision only, or, alternatively, it can be applied to the selected subdivision and, in addition, to other subdivisions of the patient's intralaminar nuclei" (col. 14, lns. 21-29). Again, nothing about this disclosure suggests direct cortical stimulation.

In sum, Schiff discloses intralaminar stimulation areas, but provides no specificity regarding other brain areas for receiving stimulation beyond the assertion that such areas exist. To the extent that Schiff discloses a connection between cortical and intralaminar nuclei functioning, he discloses identifying a cortical function and then providing stimulation at the associated intralaminar target. Based on this disclosure, one of ordinary skill in the relevant art would not be led by Schiff's disclosure to look to Firlik for disclosing a stimulation site within the patient's skull, proximate the dura mater, and outside a cortical surface of the patient's brain to receive electrical stimulation. For at least the foregoing reasons, the applied references cannot form the basis of a 103 rejection of claim 19. Accordingly, applicants respectfully request that the Section 103 rejection of claim 19 be withdrawn.

Claims 20, 22, 23, 25-27, 32 and 35-39 depend from claim 19. Independent claims 78, 79 and 86 include features generally analogous to those discussed above with reference to claim 19. Accordingly, for at least the foregoing reasons and for the additional features of these claims, the Section 103 rejections of the foregoing claims should be withdrawn.

B. Response to the Section 103 Rejections on the Basis of Schiff, Firlik '419, Firlik '201, Binder and McDermott

Independent claims 1, 40, 61, 72-76, and 80-85 all include features generally analogous to those discussed above with reference to claim 19. Binder and McDermott fail to cure the deficiencies described above with reference to Schiff, Firlik '419 and Firlik '201 as establishing a *prima facie* basis for rejecting claim 19, and therefore, the foregoing independent claims as well. Claims 4-7, 9-12, 14-18, 21, 41-43, 45-47, 49-55, and 62-70 all depend from one of the foregoing independent claims. Accordingly, the Section 103 rejections of the foregoing independent and dependent claims should be withdrawn for at least the foregoing reasons and for the additional features of these claims.

C. New Claims 87-89

New claim 87 has been added to the application and includes features generally similar to those of claim 1. In addition, new claim 87 indicates that, based at least in part on the information corresponding to a level of neural activity present in the patient's brain while the patient performs a language based task, selecting the stimulation site includes selecting all stimulation sites for receiving an electrode coupleable to an electrical current to be within the patient's skull, proximate the dura mater, and outside a cortical surface of the patient's brain (emphasis added). Schiff expressly teaches away from at least this feature of claim 87. For example, to the extent that Schiff discloses stimulating any region of the brain other than the intralaminar nuclei, Schiff specifies that such stimulation is "in addition to being applied to the patient's intralaminar nuclei or portion thereof" (Schiff at column 11, lines 29-30, emphasis added). Accordingly, Schiff expressly teaches away from the features of claim 87. Support for the features of claim 87 may be found in the application as filed at paragraph 41 (identifying embodiments of electrodes positioned at

the cortex as distinct from "other embodiments" in which the electrode assemblies can extend into or beneath the cortex). Further support may be found in Figures 4-9, all of which disclose systems in which all the stimulating electrodes are positioned within the patient's skull, proximate the dura mater and outside the cortex.

New claim 88 has been added to the application and is directed to a method for treating a patient's language disorder. The method includes identifying a specific cortical neural population that affects one or more specific language-based functions. The method further includes at least reducing effects of the patient's language disorder by applying electrical signals directly to cortical inputs at the specific cortical neural population from a location that is within the patient's skull, proximate the dura mater, and outside a cortical surface of the patient's brain. As discussed above, the teachings of Schiff would not cause one of ordinary skill in the art to look to Firlik to modify Schiff's method in a manner that includes the features of claim 88. Accordingly, for at least the reasons discussed above, claim 88 patentably defines over the applied references.

New claim 89 has been added to depend from claim 88 and includes features generally similar to those discussed above with reference to new claim 87. Accordingly, for at least the foregoing reasons and for the additional features of this claim, claim 89 patentably defines over the applied references.

D. Conclusion

The foregoing remarks addressing Firlik '419 and Firlik '201 are directed only to the disclosures of these applications, and not to the claims that have issued in these applications, or that may issue in applications claiming priority to these applications. Such claims may well encompass embodiments not specifically disclosed in these applications.

In light of the foregoing remarks, applicant's attorney respectfully requests reconsideration and allowance of all the pending claims. If the Examiner notices any informalities or other matters that may be expediently handled by telephone, she is encouraged to contact the undersigned attorney by telephone to resolve such matters.

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Respectfully submitted,

By _____

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